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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,207	09/21/2000	Kevin R. Orton	ORTONK.003A	9101

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ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/666,207

Applicant(s)

ORTON, KEVIN R.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 4, 12-21 and 29-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11 and 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 29-40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly presented methods add steps such as filling at one location, transporting the container, applying an electrical signal, and administering the fluid. These additional steps are not claimed as part of the originally claimed method.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

2. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5-11, and 22-28 are rejected under 35 U.S.C. 103(a) as obvious over US 4,822,339 to Tran. Tran discloses a container 322 with at least one wall and a cavity or a reservoir, two electrodes 324 and 326 that are spaced apart and attach from the inner wall and extend into the reservoir. The electrodes pass through the container, thereby coming into contact with the outside surface of the container, and connect to leads or contact elements 346 and 348 outside the reservoir (see FIG 1). The container further comprises a sealing element as illustrated in FIG 10 (see column 5, lines 50-60, column 10, lines 45-67, FIG 10). Tran discloses a pierceable sealing element 340 on a secondary container 338, and illustrates a seal and a pierceable closure on both the secondary container 338 and the primary container 322 (see FIG 10). The container further comprises a therapeutic agent that may be transferred to a patient (see FIGS 1, 2, and 10, column 8, lines 18-29). Tran discloses that while the apparatus holds a liquid, an electrical charge is applied between the electrodes, and the therapeutic agent is then transferred to the patient by appropriate delivery means, which includes an "applicator" as claimed by applicant. Tran further discloses an alternate embodiment of the container (see FIG 3) that includes both electrodes in a single undivided chamber 218

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defined by housing 228. See FIG 3, column 9, lines 62-67. The housing comprises a membrane which is "substantially impermeable" to certain substances.

Tran fails to disclose that the sealing portion is "cooperating" with the outside surface of the container. However, as illustrated in FIGS 1 and 10, the sealing portion of the Tran device is flush with the outer surface of the container, sealing the container up to the outside surface and protecting from contamination. Since both sealing portions protect the containers from contamination and seal to the outside surface of the container, the sealing portion of the Tran device "cooperates" with the outside surface of the container in that it works along with the container to protect from contamination. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the sealing portion of the Tran device to "cooperate" with the outside surface of the container, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

With regard to applicant's claim that the sealing portion is "adapted to" reseal, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Response to Amendment/Arguments

5. Applicant's amendment and arguments filed 26 April 2005 have been fully considered but they are not persuasive. Applicant merely claims a "substantially

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impermeable" reservoir, which does not mean that the membrane is completely impermeable. Substantially permeable means that portions of the reservoir retain permeability, rendering the instant invention unpatentable over the Tran reference. Furthermore, applicant claims the step of applying an electric current to enhance the therapeutic effectiveness of the fluid. Tran applies electric current to move ions across the membrane to create a therapeutic agent for delivery to a patient. Such a procedure improves the therapeutic value of the fluid to the patient, thereby rendering applicant's invention unpatentable over the Tran device.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
12 July 2005


PATRICIA BIANCO
PRIMARY EXAMINER
7/14/05